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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,000	06/19/2007	W Michael Kavanaugh	CHIR0006-101	5426

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,000	KAVANAUGH ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/14/2010, 6/30/10, 5/4/10, 3/31/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *149-153,155 and 157-196* is/are pending in the application.

4a) Of the above claim(s) *164, 166, 172, 174, and 175-196* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *149-153, 155, 157-163, 165, 167-171, 173, and 176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/06, 3/14/07, 4/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 149-153, 155, 157-196 are pending.

Drawings

The drawings are objected to because of the reasons below:

Figure 8, the photograph is essentially illegible. Figure 10A, 10B the markings for two of the samples are invisible (BV762 supernatant, Uninfected supernatant). Figure 13, the print is too small to be legible, and two of the samples are invisible. Figures 15, 17 and 18, the gray background makes the graph or the text difficult to see. Figure 19, the print is too small to be legible. Figure 20, one sample is invisible (No BV with PBMCs).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Election/Restrictions

Claims 176-196 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 164, 166, 172, 174, and 175 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/4/2010, and the traversal was not found persuasive in the communication mailed 9/3/2010.

The requirement is still deemed proper and is therefore made FINAL.

The elected species are: lung cancer disease, tumor growth symptom, UV-inactivated or UV+ Psoralen-inactivated viral particle, co-administered with an anti-cancer drug. The specification defines “virus particle” as “a virus that has been constructed, or modified from its native form, whereby it is unable to replicate in naturally occurring host cells.” So the term “virus particle” is seen as encompassing both replication-defective mutant (live) virus and inactivated virus.

Claim Objections

Applicant is advised that should claims 150, 151 be found allowable, claims 159, 160 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, 2nd

Claims 149-153, 155, 157-163, 165, 167-171, 173, and 176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 149 is drawn to a body-treating process to treat or prevent cancer, that involves administering a non-pathogenic insect-specific virus to an animal. This appears clear at first glance, but the intended scope becomes less clear upon reading the specification. The specification defines the term "virus" as encompassing "live virus, inactivated virus, virus particles, viral occlusion bodies, virosomes, Viral Like Particles, viral components." Therefore, the term "virus" in the claims is confusing to one skilled in the art, as the meaning as defined in the specification is much more broad than the ordinary meaning of the term to one skilled in the art. The intended scope of the term "viral components" is also unclear; claim 166 indicates that the term includes nucleic acid, lipid, and carbohydrate. But lipids and carbohydrates are typically "hijacked" from host cells, and are not specific to the virus, so it is not clear what insect cell components are meant to be included in the claimed subject matter. These problems affect dependent claims.

For claims 150 and 160, the specification defines a PFU equivalent for an inactivated virus, but it is not clear what is a PFU equivalent for a virosome or a virus-like particle or a viral component. Also, it is not clear if claims 150 and 160 refer to the

total amount of virus used in the method, or if they refer to the specific activity of the virus used in the method. Furthermore, the claims require <500,000 pfu or equivalents to kill >50% of the cells in an in vitro assay, but they do not state how many cells are in the assay, or what kind of cells are in the assay. Since different types of cells (e.g., human neurons, chicken fibroblasts, caterpillar cells) are likely to respond differently to the same amount of virus, both the number and type of cells exposed to the 500,000 pfu affect whether or not >50% of the cells die.

For claim 158, it is not clear if the intent is to inactivate virus components such as isolated nucleic acids, as well as inactivating living viruses.

In claim 165, it is not clear what "gp64" means in the context of the broadly claimed nonpathogenic insect virus of the parent claim. Is a baculovirus gp64 actually intended?

Claim Rejections - 35 USC § 112, 1st, description

Claims 149, 150, 155, 157, 158, 160-163, 165, 167-171, 173, and 176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a method of treating or preventing cancer, using a non-pathogenic, insect-specific virus to treat an animal. This involves the genus of non-pathogenic, insect-specific viruses. As discussed in the review by Friesen, this is a large genus encompassing viruses from numerous taxonomic families,

with widely differing characteristics. The specification reduces to practice a treatment method using one species of virus, baculovirus. Considering the variety of nonpathogenic insect viruses, the inability to predict which other viruses, if any, have the same anticancer effects, the absence of teachings regarding what characteristics of baculovirus are responsible for the anticancer effect (and therefore the absence of a correlation between the structure of an insect virus and the anti-cancer function), it is concluded that the specification does not reasonably convey possession of the method claimed for the broad genus of nonpathogenic insect viruses.

Claim Rejections - 35 USC § 112, 1st, enablement

Claims 149-153, 155, 157-163, 165, 167-171, 173, and 176 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cancer comprising intratumoral or peritumoral delivery of inactivated baculovirus, does not reasonably provide enablement for the full scope of treatment and prevention methods using virus particles of any nonpathogenic insect-specific virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The species elected for examination is “viral particle”, which encompasses replication-defective mutant (live) virus and inactivated virus, as discussed above under “Elections/restrictions.” The invention, as broadly claimed, involves viral particles of any nonpathogenic insect-specific virus. As discussed above, the nonpathogenic insect-specific viruses come from numerous taxonomic families, with widely differing

characteristics. The invention, as broadly claimed, also involves preventing any and all types of cancer, and treating any and all types of cancer, and using any and all routes of administration. The specification shows that inactivated baculovirus induce PBMC-mediated tumor cell killing for cells directly contacted with the virus, and for bystander cells in the vicinity of the contacted cells. The specification also shows inhibition of lung tumor growth with intratumoral administration of the inactivated virus. However, there is no showing of similar effects throughout the broad scope of insect viruses, or for cancers that are not subjected to direct contact with the inactivated virus, or for any preventive effect. Considering the broad scope of the claims, the unpredictability of the cancer treatment art, the limited teachings in the specification, and the limited scope of the working examples, it is concluded that undue experimentation would be required to enable the full scope of the invention as claimed, even for the elected species of "viral particle."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).,

Claims 149-153, 155, 157, 159, 160-163, 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blissard et al US 6607912 in view of Maitland et al US 2005/0009184. As discussed above, the elected species of "virus particle" is encompasses replication-defective mutant (live) virus. Blissard teaches replication-defective baculovirus, made by deleing an envelope protein gene such as gp64, and providing a heterologous targeting glycoprotein, such as the VSV G protein. Blissard teaches as an advantage, that the pseudotyped viruses are likely to be less susceptible to complement inactivation in vivo, see column 3 lines 8-19. This differs from the claimed invention in that Blissard does not suggest cancer treatment with the recombinant virus. However, Maitland teaches baculovirus engineered with cancer-cell specific promoters, tumor suppressor polypeptides, tumor rejection antigens, cytotoxic products, anti-angiogenesis products, and apoptosis-inducing products, see for example paragraphs 24-43, and treatment of cancer, see for example paragraph 58-60. It would have been within the ordinary skill of the art to incorporate the cancer-treatment elements of Maitland for expression in the baculovirus construct of Blissard, and to use the resulting baculovirus to treat cancer, with reasonable expectation of success. Although neither reference specifically discusses a route of administration or combination therapy, administering an expression vector in or near the tumor would

have been a matter of common sense, as would have been the use of additional anti-cancer therapeutics. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 149-153, 155, 147, 159, 160, 163, 165, 167, 168, 171, 173 are rejected under 35 U.S.C. 102(b) as being anticipated by Rueda et al (Vaccine 19:726-743, 2001; in IDS). These claims involve prevention of cancer by administering an effective amount of an inactivated baculovirus. The specification does not teach a specific amount is needed to be effective; therefore, a reference teaching administering inactivated baculovirus to a mammal is seen as meeting the claim requirements for the "preventing cancer" aspect of the invention. Rueda teaches administering a composition comprising inactivated baculovirus to guinea pigs, see section 3.7 on pages 731-732. Although Rueda does not teach that the administration prevents cancer, this would be an inherent outcome of the process, since the process involves the same inactivating and administering steps as required by the claims.

Information Disclosure Statement

The information disclosure statement filed 3/14/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each

non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered, for the document lined out on the 1449 form. Applicants apparently submitted a CD-ROM containing the documents; unfortunately, the PTO does not provide for transferring documents from a CD-ROM to the image file record. Therefore the documents have not been considered.

The following additional references are cited as of interest. Hilbert et al US 6001806 teaches that the baculovirus gp64 protein has interferon-stimulating anticancer activity, see the abstract for example. Rueda et al (Vaccine 19:726-743, 2001; in IDS) and Weightman et al (Journal of Virological Methods 81:179-182, 1999; in IDS) teach inactivation of baculoviruses contaminating compositions of recombinant proteins made from a baculovirus expression vector.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is (571)272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

11/29/10